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1631

Attorney Docket No.: 19459-006US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Shiau et al.	Art Unit	: 1631
Serial No.	: 09/830,693	Examiner	: Nashaat T. Nashed
Filed	: March 30, 1999 (§371 date: January 29, 2002)	Confirmation No.	9894
Title	: METHODS AND COMPOUNDS FOR MODULATING NUCLEAR RECEPTOR ACTIVITY		

RESPONSE TO DECISION ON PETITION FROM REQUIREMENT FOR RESTRICTION UNDER 37 CFR § 1.144

Director
Technology Center 1600: ***Attn. Special Program Examiner***
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants are in receipt of the Decision on Petition ("Decision") dated August 2, 2005 in connection with the above-identified patent application.

Applicants now request reconsideration of the Decision, in part. The instant request is being filed on the first business day following the date that is two months from the date of the Decision, pursuant to the condition specified on page 5 of the Decision.

Specifically, Applicants thank the Office for granting Applicants' request for joinder of Groups V and VII in the instant prosecution. However, Applicants now respectfully request reconsideration of the Office's denial to consider joinder of claims 1–25, 29–35, 39, 52–133, and 140–141, from Groups I, II, III, and VIII, into a single group under the Unity of Invention standard, for reasons discussed hereinbelow.

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Background to Petition

The pertinent details of the prosecution history of the instant application have been presented in both the Decision, and Applicants' original Petition from Requirement for Restriction under 37 C.F.R. § 1.144, dated March 9, 2005 ("Petition"), and thus are not repeated here, except to summarize, as follows. The instant application is a U.S. national phase application of PCT/US99/06937, filed March 30, 1999. Following an initial restriction into 10 groups, dated June 25, 2004, to which Applicants responded with a provisional election and traverse on August 19, 2004, a revised restriction into eight (8) groups of claims was mailed December 9, 2004, and made final. Applicants' Petition was timely filed in response, on March 9, 2005, and the Office's adjudication of said Petition was presented in the Decision of August 2, 2005.

Request for Consideration and Reasons Therefor

The essence of Applicants' instant response and request for reconsideration of the Decision is as follows: Applicants respectfully disagree with the Office's assertion that, had Applicants "elected one of groups I, II, III, or VIII and traversed the lack of unity determination, the traversal would have been non-persuasive" (Decision, at page 3). Applicants respectfully submit that the quoted assertion is predicated on an incorrect reading of 37 C.F.R. § 1.475 ("Rule 475", hereinafter).

As previously acknowledged, the "unity of invention" standard under PCT Rules 13.1 and 13.2 is applicable to the instant application because it is a U.S. national phase application under 35 U.S.C. § 371. Under such a standard, unity of invention exists for claims that possess one or more "special technical features" in common. See Rule 475(a).

Applicants have previously argued that all claims in Groups I, II, III and VIII, except for claims 134 and 135, should be joined into a single group under the applicable Unity of Invention standard because they possess the following special technical features:

> an atomic structural model of the estrogen receptor ligand binding domain, comprising atomic coordinates of:
> helix 12 of the ligand binding domain;
> a coactivator binding site, and
> a coactivator bound to the coactivator binding site.

Indeed, this characterization is, as previously discussed (Petition, page 2), congruent

with the Examiner's own identification of a "special technical feature" in the claims of Groups I, III and VIII, and at least claims 29–33 and 67–71 of Group II.

In the Decision, however, the Office has cast the claims as being of different categories to one another. For example, according to the Office "Groups I, II, and VIII are each drawn to different methods requiring different steps and Group III is drawn to a machine readable storage device not required to be made by or required to be used in any of the methods of Groups I, II or VIII." (Decision, at bottom of page 3).

In support of the Office's analytical framework, Rule 475 is cited in its entirety, followed by a conclusion that:

> "[a]s stated above, a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to *only* one of the listed combinations of categories *** This [sic] Groups I, II and VIII are drawn to different method [sic] that do not share unity of invention and are not linked as a main invention." (emphasis added)

(Decision, top of page 5). Applicants' respectfully submit that this characterization of Rule 475 is both contrary to its plain language and to the spirit with which it was enacted.

The "listed combinations of categories" referenced by the Office are found in Rule 475(b). First, Applicants point out that Rule 475(b) is not an exclusive list. Rule 475(b) states that the listed categories are those for which unity of invention *will* be found. When taken together with the remainder of Rule 475, Rule 475(b) does not state, as the Office implies in the Decision, that unity of invention will *only* be found for such categories of inventions. For example, Rule 475(a) sets forth the requirement of "special technical features", which informs the rest of Rule 475. The requirement of Rule 475(a) would be vitiated under the Office's narrow construction of Rule 475(b) in the Decision. Furthermore, Rule 475(c) allows that "unity of invention *might* not be present" in "an application [that] contains claims to more or less than one of the combinations of categories [in Rule 475(b)]" (emphasis added). If the Office's construction of Rule 475(b) in the Decision were reasonable, unity of invention could never be present in applications referred to under Rule 475(c) and thus Rule 475(c) would never have force.

Furthermore, Applicants respectfully draw the Office's attention to the Office's own remarks presented at the time of establishment of the present form of Rule 475. *See* Federal

Register, January 14, 1993. Thus, in remarks explaining the amendments to Rule 475, the Office stated as follows:

> Section 1.475(b) is amended to define several combinations of different categories of claims which always fulfill the unity of invention requirements of § 1.475(a) where the same or corresponding special technical feature is claimed. *There may be other combinations of different categories of claims which fulfill the requirement for unity of invention, but the determination of unity must be made under § 1.475(a), not § 1.475(b).* (emphasis added)

58 FR 4335, at page 4342. Thus, as can be seen from remarks accompanying its most recent amendments, Rule 475(b) was not intended to have an exclusive construction. Furthermore, the import of assessing unity of invention by the standard of Rule 475(a), rather than a restrictive reading of Rule 475(b), was also emphasized by the Office:

> Section 1.475(c) is amended to require that unity of invention might not be present if a combination of categories of invention different from those described in § 1.475(b) are presented in an application. The requirements of § 1.475(a) are always met by the combinations described in § 1.475(b) where the same or corresponding special technical feature is claimed. *All other combination [sic] must be tested against the unity of invention standard of § 1.475(a).*

58 FR 4335, at page 4342. Thus combinations other than those listed in Rule 475(b) were contemplated to be consistent with a unity of invention determination.

Accordingly, Applicants respectfully submit that the claims of groups I, III, and VIII, as well as at least claims 29–33, and 67–71 in Group II, should have been joined under a Unity of Invention standard under Rule 475(a) applicable to the instant application. Therefore, Applicants respectfully request a favorable determination by the Office in this regard.

Applicants reassert that the arguments presented herein are not be construed as an admission that any of the claims of any of groups I, II, III, and VIII are obvious over, or are not patentably distinct from, the claims of any other of such groups, or that the claims of Group V are obvious over, or are not patentably distinct from, the claims of Group VII.

(SIGNATURE BLOCK AND FEE AUTHORIZATION ON NEXT SHEET)

Conclusion

No fee is believed owing with this response. However, should the Commissioner determine otherwise, he is authorized to charge any required fee to Fish & Richardson P.C. Deposit Account No. 06-1050 (order no. 19459-006US1). A copy of this sheet is enclosed.

Respectfully submitted,

Date: October 3, 2005

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